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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,774	07/25/2001	Manaud Pierre Frederic De Raspide	PC10915A	5154

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,774	DE RASPIDE ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *0316/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 15-42* is/are rejected.

7)☒ Claim(s) *11-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 03/16/04.

Applicants' experiment submitted with the amendment of 03/16/04

Examiner acknowledges the submission of the new experimental data to show the teaching of the WO 00/06161 apart from the instant claims. However the following observation is made:

a) The showing is not a signed declaration

b) The comparison is not clear

It is suggested that appropriate and clear comparison be submitted as a signed declaration.

Drawings

1. The drawings filed 07/25/2001 are objected to as failing to comply with 37 CFR 1.84. Copy of Patent Drawing Review is attached. Correction is respectfully requested.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 32-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the recurrence of migraine, does not reasonably provide enablement for preventing migraine recurrence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors are considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

I) Nature of invention.

II) State of prior art.

III) Level of ordinary skill in the art.

IV) Level of predictability in the art.

V) Amount of direction and guidance provided by the inventor.

VI) Existence of working examples

VII) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

I. Nature of the invention:

The claims are drawn to method for treating migraine with therapeutically effective amount of eletriptan containing composition. Applicants' specification does not discuss or show with data how the recurrence of migraine has been kept from happening.

II. State of the prior art:

The prior art does not disclose case(es) supported data showing that the recurrence of migraine has been kept from happening and how long has the recurrence of the migraine stopped

from happening and in how many subjects has this recurrence exclusion been observed and for how long has the recurrence been stopped by the administration of eletriptan.

III. Level of Ordinary Skill in the art:

The level of ordinary skill in the art is high. Applicants' specification does not enable the public to practice the art of keeping recurrence of migraine form happening.

IV. Level of predictability:

Since applicants' specification does not show the stoppage or exclusion or keeping migraine recurrence and for how long challenges the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention with little or no predictability. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants.

V. Amount of direction and guidance provided by the inventors:

The amount of direction and guidance provided by the applicants is limited to treatment. There is no evidence in the specification that established correlation between administration of eletriptan and migraine that has been kept from totally recurring. See Ex parte Mass, 9 USPQ2d 1746, 1987.

VI. Existence of working examples:

Applicants' specification exemplifies preparation of the composition and does not provide a showing of the number and extent and duration that migraines have been kept from recurring.

VII. Quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The quantity of experimentation required to use the invention as claimed, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experimentation with a large number of subjects and for reliable duration of time during which the eletriptan containing composition is administered to keep the recurrence of the migraine from happening.

5. Claims 15, 16, 19-26, 28-31, 38, 39 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, 16 and 19 contain the trademark/trade name EUDRAGIT in the RS and RL forms. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe acrylic polymers containing ammonium groups and, accordingly, the identification/description is indefinite.

6. Regarding claims 20 and 21, the term "other" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 26 is vague and indefinite because it is not clear where the thought terminated because the essence of the dual release formulation is not clear.

Claims 38 and 39 are unclear because it is not clear in claim 38 how delivery of eletriptan into an aqueous solution is the same as delivering eletriptan to a mammal; and it is confusing in claim 39 as to what happens to the delivery process of the eletriptan after "mammal" in line 2 of the claim.

Claim 42 is confusing because the amendment deletes "comprising" in line 5, but does not replace or substitute the "comprising" with any word leaving the claim to hang. It appears that consisting is missing.

Claim 19 depends from amended claim 1. In amended claim 1, the coating composition consists of one or more acrylic copolymer and the consisting language limits the coating to acrylic copolymer. The coating composition in claim 9 now includes talc and triethyl citrate that is excluded by the claim language of amended claim 1.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 40 is rejected under 35 U.S.C. 102(a) as being anticipated by Jackson et al. (WO 00/06161).

Jackson discloses a pharmaceutical composition comprising eletriptan (abstract). No amount of eletriptan is disclosed in the claims. Jackson meets the limitation of the claim.

9. Claims 1, 4, 15, 27, 32 and 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Cherukuri et al. (US 2002/0044962).

Cherukuri discloses a controlled release composition comprising at least one active agent, at least one erodible polymer and at least one lubricating agent and the composition is formed as a caplet (abstract, paragraphs [0022]-[0026]); the core of the composition comprises the active agent (paragraph [0070]). Eletriptan, an agent active in the management of migraine is one of the active agents that can be formulated according to the Cherukuri (paragraph [0098] and claim 30). The caplets of Cherukuri are coated with a composition of EUDRAGIT RS and dibutylphthalate plasticizer (paragraph [0161]). Suitable for oral administration as recited in the instant claim 1 is an intended use and also a route of administration, both of which are not given patentable weight since intended use is not critical to a composition claim. Capable of achieving a sigmoidal pattern of controlled drug release is an inherent property of the composition and the property of a composition cannot be separated from the composition. Cherukuri meets the limitations of the claims.

Claim Rejections - 35 USC § 103

10. Claims 1-10 and 15-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 00/06161) in view of Stevens et al. (US 5,112,621).

Applicants argue that the reference of the WO 00/06161 (Jackson et al.) to US 5,112,621 (Stevens et al.) is to the invention in Stevens that has the coating composition comprising EUDRAGIT and ethylcellulose and the reference to a coating of EUDRAGIT alone is for comparison purposes.

11. Applicants' arguments filed 03/16/04 have been fully considered but they are not persuasive.

Although, Stevens may have mentioned a coating composition that comprises EUDRAGIT alone for comparison, there is a disclosure of a coating composition that has EUDRAGIT as the sole polymer. Applicants provided experimental data to show that using the eletriptan in the composition of Stevens does not produce a sigmoidal response. However, as indicated above, the data submitted is not signed and a signed declaration would be necessary. Secondly, it is not clear from the data if the composition of Jackson is coated with the coating composition as suggested by Stevens in column 3, lines 13 and 14. Thus, the data may have to be clarified when submitting a signed declaration.

12. Claims 1-10, 15-39, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 00/06161) in view of Cherukuri et al. (US 2002/0055962).

Jackson discloses controlled or sustained or pulsed release composition that contains eletriptan (abstract). Jackson discloses that both hydrobromide salt and hemisulfate form of the eletriptan are known in the art (page 1, lines 9-13). Jackson, by incorporating the Stevens reference suggests a coating composition that contains EUDRAGIT. And Cherukuri discloses coating a composition that contains eletriptan with a coating composition of EUDRAGIT and plasticizer. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use prepare and use the eletriptan composition of Jackson. One having ordinary skill in the art would have been motivated to coat the composition of Jackson according to the disclosure of Cherukuri by coating the eletriptan composition of Jackson with a coating composition of EUDRAGIT and plasticizer with the expectation of realizing the desired release pattern as modified by the EUDRAGIT.

13. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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